**BRITISH STANDARD**

**BS EN 1281-1 : 1997**

*Incorporating Amendment No. 1*

# Anaesthetic and respiratory equipment — Conical connectors

## Part 1. Cones and sockets

The European Standard EN 1281-1 : 1997, with the incorporation of its amendment A1 : 1998, has the status of a British Standard

ICS 11.040.10

**BS EN 1281-1 : 1997** Issue 2, December 1998

# Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/44, Anaesthetic machines, breathing attachments, medical gas pipeline systems and hose assemblies, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
Association of British Health-care Industries
British Anaesthetic and Respiratory Equipment Manufacturers' Association
Department of Health

The following body was also represented in the drafting of the standard, through a subcommittee/panel:

Guild of Hospital Pharmacists

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 May 1997



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|---|---|---|
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The following BSI references relate to the work on this standard:
Committee reference CH/44
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## Summary of pages

The following table identifies the current issue of each page. Issue 1 indicates that a page has been introduced for the first time by amendment. Subsequent issue numbers indicate an updated page. Vertical sidelining on replacement pages indicates the most recent changes (amendment, addition, deletion).

| Page | Issue | Page | Issue |
|---|---|---|---|
| Front cover | 2 | 2 | 2 |
| Inside front cover | 2 | 3 | 2 |
| a | 1 | 4 | original |
| b | blank | 5 | 2 |
| i | original | 6 to 12 | original |
| ii | 2 | Inside back cover | 2 |
| EN title page | 2 | Back cover | 2 |

# Contents

# National foreword

This British Standard has been prepared by Technical Committee CH/44 and is the English language version of EN 1281 *Anaesthetic and respiratory equipment — Conical connectors* — Part 1 : 1997 *Cones and sockets*, including Amendment A1 : 1998, published by the European Committee for Standardization (CEN).

This standard supersedes BS 3849 : Part 1 : 1988 which is withdrawn. Together with BS EN 1281-2 : 1996, this standard supersedes BS 3849 : Part 2 : 1988 which is withdrawn.

**Cross-references**

| International Standard | Corresponding British Standard |
|---|---|
| EN ISO 4135 : 1996 | BS EN ISO 4135 : 1996 *Glossary of terms used in anaesthesiology* (Identical) |
| EN 60601-1 : 1990 | BS 5724 *Medical electrical equipment* Part 1 : 1989 *General requirements for safety* (Identical) |

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EUROPEAN STANDARD
NORME EUROPÉENNE
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# EN 1281-1

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+ A1

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Descriptors: Medical equipment, anaesthetic equipment, artificial breathing apparatus, fittings, conical clamping connections, specifications, dimensions, dimensional measurements, standard gauges, junctions, tests, marking

English version

# Anaesthetic and respiratory equipment — Conical connectors — Part 1 : Cones and sockets

(includes amendment A1 : 1998)

Matériel respiratoire et d'anesthésie — Raccords coniques — Partie 1 : Raccords mâles et femelles (inclut l'amendement A1 : 1998)

Anästhesie- und Beatmungsgeräte — Konische Konnektoren — Teil 1 : Männliche und weibliche Konen (enthält Änderung A1 : 1998)

This European Standard was approved by CEN on 1996-12-15; amendment A1 was approved by CEN on 1998-05-03. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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**CEN**

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

**Central Secretariat: rue de Stassart 36, B-1050 Brussels**



Ref. No. EN 1281-1 : 1997 + A1 : 1998 E

## Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This European Standard is based on ISO 5356-1 : 1993, prepared by Technical Committee ISO/TC 121 of the International Organization for Standardization (ISO).

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EU directives, see informative annex ZA, which is an integral part of this standard.

This European Standard applies to conical connectors for anaesthetic and respiratory equipment and has been prepared in two Parts. This Part addresses cones and sockets; Part 2 addresses screw-threaded weight-bearing connectors.

Annexes B, C, D and E are normative and form part of this European Standard. Annexes A, F, G and ZA are for information only.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

## Foreword to amendment A1

This Amendment EN 1281-1 : 1997/A1 : 1998 to EN 1281-1 : 1997 has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This Amendment to the European Standard EN 1281-1 : 1997 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

This Amendment to the European Standard EN 1281-1 : 1997 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 1998, and conflicting national standards shall be withdrawn at the latest by November 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

## Contents

## Introduction

This European Standard specifies dimensional requirements for conical connectors used in anaesthetic and respiratory equipment.

The standard comprises two Parts:

Part 1 : Cones and sockets

Part 2 : Screw-threaded weight-bearing connectors.

In clinical practice several breathing attachments may have to be joined together to provide a suitable breathing system. Items of medical equipment, such as a humidifier or a spirometer, are often incorporated into the breathing system which may also be connected to an anaesthetic gas scavenging system. Connections for these purposes are usually, though not invariably, cone and socket joints and a lack of standardization of these connections has given rise to problems of interchangeability when connecting equipment made by different manufacturers.

This Part of the standard gives the requirements for the following conical connectors:

- 8,5 mm sizes intended for use in paediatric breathing systems;[1)]
- 15 mm and 22 mm sizes intended for general use in breathing systems;[2)]
- 23 mm size intended for use with vaporizers[3)], which are unsuitable for use in breathing systems;
- 30 mm size intended for the connection of a breathing system to an anaesthetic gas scavenging system.[4)]

An important consideration is that conical connections should be secure but nevertheless disconnectable by the operator. The use of connectors meeting the requirements of this Part of the standard will not necessarily prevent them being disconnected accidentally.

This Part of this European Standard specifies the performance of latching connectors of 22 mm size.

Annex A (informative) includes a figure and a table detailing plug and ring test gauges that may be used to check the sizes of metal conical connectors. It is provided for information only and is not a normative part of the standard.

Annex B (normative) includes a figure and a table detailing plug and ring test gauges that are used to check the sizes of conical connectors made of materials other than metal.

Figure 1 detailing the dimensions and tolerances of metal conical connectors has been prepared in accordance with the principles given in ISO 3040.

Requirements and application of conical connectors are not included in this Part of this European Standard but are given in particular European Standards for specific medical devices and accessories (see notes and annex G (informative)).

## 1 Scope

This Part of this European Standard specifies dimensional and gauging requirements for cones and sockets and performance requirements for latching connectors intended for use in medical devices, e.g. in breathing systems, anaesthetic gas scavenging systems and vaporizers.

This European Standard does not specify the medical devices and accessories on which these connectors are to be provided.

NOTE 1. It is expected that requirements on the use of suitable materials and for the application of this standard will be included in particular standards for specific medical devices and accessories.

NOTE 2. Requirements for screw-threaded weight-bearing conical connectors are specified in Part 2 of this standard.

## 2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

| | |
|---|---|
| EN ISO 4135<br>(ISO 4135 : 1995) | *Anaesthesiology vocabulary* |
| prEN 12342 | *Breathing tubes intended for use with anaesthetic apparatus and ventilators* |
| EN 60601-1 : 1990<br>(IEC 601-1 : 1988) | *Medical electrical equipment Part 1: General requirements for safety* |

[1)] See e.g. EN 1780 and bibliography.

[2)] See e.g. clause **63.1.7.1** and **66** of prEN 740 : 1992 and bibliography.

[3)] See e.g. clause **64.1.1** of prEN 740 : 1992 and bibliography.

[4)] See e.g. clause **70.5** of prEN 740 : 1992 and bibliography.

## 3 Definitions

For the purposes of this European Standard, the following definition applies, in addition to those given in EN ISO 4135.

### 3.1 latching connector

Female connector for engagement with a male conical connector complying to this standard, which has a feature to reduce the possibility of accidental disconnection.

## 4 Antistatic and electrically conductive connectors

See appropriate device standards for specific requirements.

## 5 Materials

See appropriate device standards for specific requirements.

## 6 Conical connectors made of metal

### 6.1 General requirements

The dimensions of conical connectors made of metal shall be as shown in figure 1, figure 2 and table 1.

NOTE 1. See annex A for dimensions of plug and ring gauges.

NOTE 2. Metal connectors include those made of composite materials in which the mating surfaces are metal.

NOTE 3. Conical connectors of 30 mm size are intended for use for the connection of a breathing system to a anaesthetic gas scavenging system.

### 6.2 Additional requirements for conical connectors of 8,5 mm size

The male conical connector shall have a minimum inside diameter of 6 mm extending inward for at least 6 mm from the end of the connector.

### 6.3 Additional requirements for conical connectors of 22 mm size

**6.3.1** Male conical connectors of 22 mm size, with the exception of those intended for connection to a face mask, shall incorporate the recess as shown in figure 2a).

NOTE. The recess shown in figure 2a) is to accommodate the end of a female connector made of elastomeric material[5] or to permit the fitting of other devices to improve the attachment of the socket to the male conical connector e.g. a latching connector (see clause **8**).

**6.3.2** All male connectors to which it is intended to attach a face mask shall incorporate a shoulder or equivalent construction as in figure 2b).

**6.3.3** If a circumferential groove or grooves are incorporated in the surface of such a male conical connector, the total width of the groove or grooves at the surface shall not exceed 8 mm.

## 7 Conical connectors made of materials other than metal

### 7.1 General requirements

Conical connectors, made of materials other than metal shall meet the following requirements when they are type tested with gauges having dimensions as shown in figure B.1 and table B.1.

a) Conical connectors made of materials other than metal shall meet the dimensional requirements in figure 1 and table 1 with the exception that dimensions A, B and F may be varied from those shown.

b) When the connector is engaged in the appropriate plug or ring test gauge shown in figure B.1 and table B.1, by applying an axial force of $(35 \pm 3{,}5)$ N for 8,5 mm and 15 mm connectors and $(50 \pm 5)$ N for 22 mm and 30 mm connectors and, while maintaining the same force, rotating the connector up to 20°, its leading edge shall lie between the minimum and maximum diameter steps of the gauge. The connectors and gauges shall be maintained at a temperature of $(20 \pm 3)$ °C during the test.

NOTE. Because connectors made from plastics materials, for example from polyamide, polyacetal, polycarbonate, polysulfone, etc., may vary greatly in their physical characteristics, it is not considered practicable to specify their dimensions; for this reason, gauging requirements have been included. It is also considered impracticable to generalize on matters such as cold flow and thermal instability as well as possible changes in physical characteristics, contact with solvents, etc. It is, therefore, the responsibility of the manufacturer to ensure that adequate tests have been carried out to prove as far as possible that the particular materials are suitable. See also the note to clause **5**.

### 7.2 Additional requirements for conical connectors of 8,5 mm size

The requirements of clause **6.2** apply.

### 7.3 Additional requirements for conical connectors of 22 mm size

The requirements of clause **6.3** apply.

## 8 Latching connectors of 22 mm size

**8.1** The latching connector of 22 mm size shall engage with the 22 mm male connector with a recess as specified in figure 2a).

[5] The term 'elastomeric material' includes soft rubber (natural or synthetic) and some soft plastic materials, for example polyvinyl chloride, low-density polyethylene and silicone rubber.

**8.2** When tested as described in annex C the engaged connection shall not become disconnected.

**8.3** When tested as described in annex D the leakage from the engaged connectors shall not exceed 5 ml/min (corrected to 20 °C and 101,3 kPa).

**8.4** After being subjected to the procedure described in annex E the latching connector shall still meet the requirements specified in clauses **8.1, 8.2 and 8.3.**

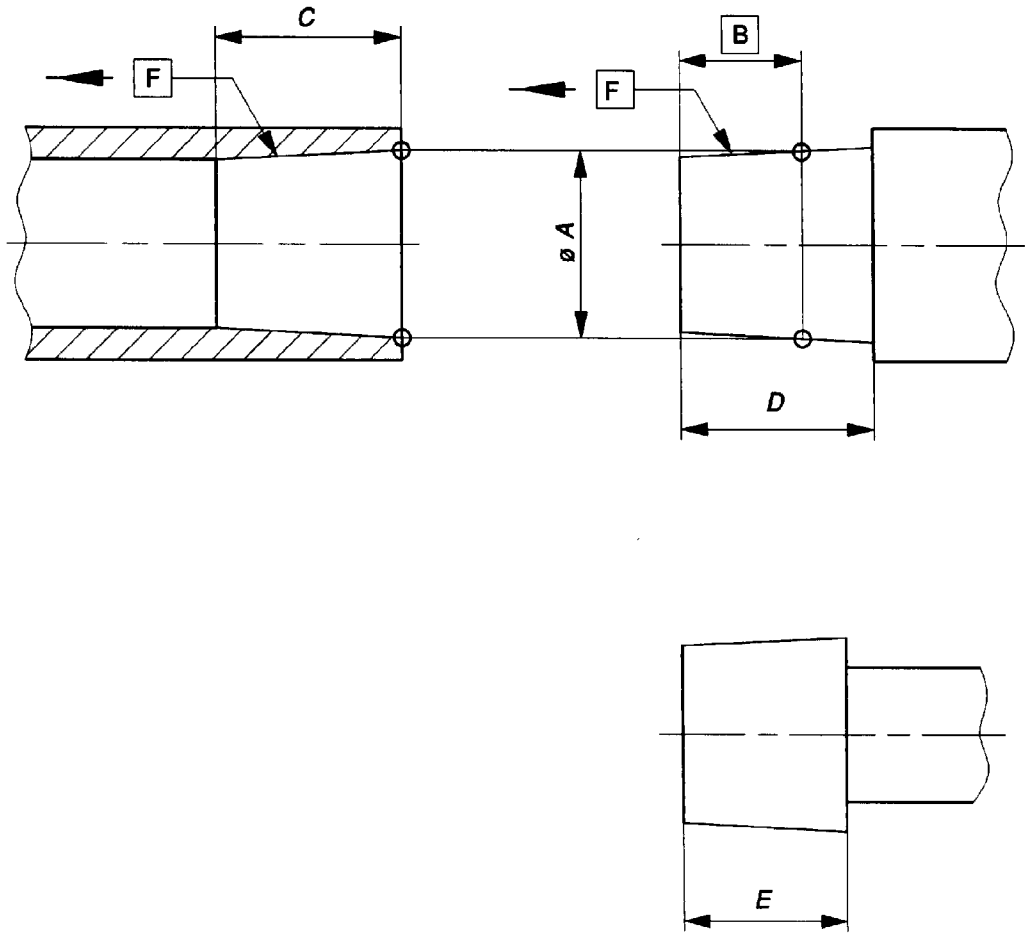
**8.5** Latching connectors intended for re-use shall meet the requirements specified in clauses **8.1, 8.2, 8.3** and **8.4** after being subjected to the cleaning, disinfection or sterilization procedures specified in clause **44.7** of EN 60601-1.

## 9 Marking

See appropriate device standards for specific requirements.

## 10 Information to be supplied by the manufacturer

See appropriate device standards for specific requirements.



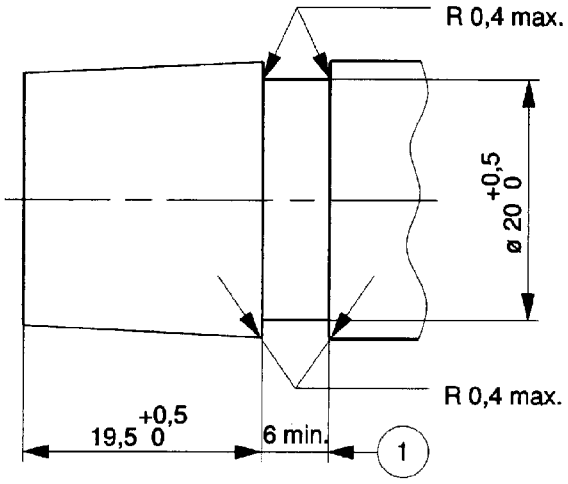

Dimensions in millimetres

NOTE. Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0,8 mm and not be less than 0,5 mm for 22 mm cones and sockets. For all other cones and sockets it should not exceed 0,5 mm and not be less than 0,2 mm.

**Figure 1. Conical connectors made of metal — Dimensions**

**Table 1. Conical connectors made of metal — Dimensions**

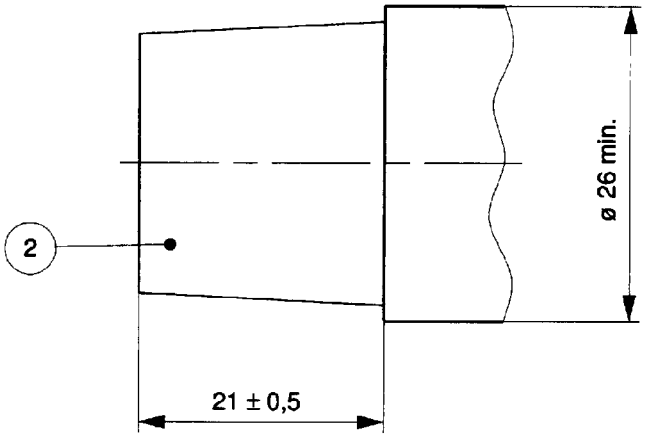
| Connector | A (mm) | B (mm) | C Min. length of taper (mm) | D Clearance to shoulder (if present) (mm) | E Min. length of taper (mm) | F |
|---|---|---|---|---|---|---|
| 8,5 mm | 8,45 ± 0,04 | 6 | 6,4 | 8,9 min. | 8 | 1:19 |
| 15 mm | 15,47 ± 0,04 | 10 | 16 | 16 min. | 14,5 | 1:40 |
| 22 mm | 22,37 ± 0,04 | 15 | 21 | See figure 2 | See figure 2 | 1:40 |
| 23 mm | 23,175 ± 0,02 | 13 | 18 | 18 min. | 15 | 1:36 |
| 30 mm | 30,9 ± 0,05 | 14 | 18 | 18 min. | 14 | 1:20 |




Dimensions in millimetres

1. To shoulder (if present)

Figure 2a). Connector intended for breathing attachment (with recess)



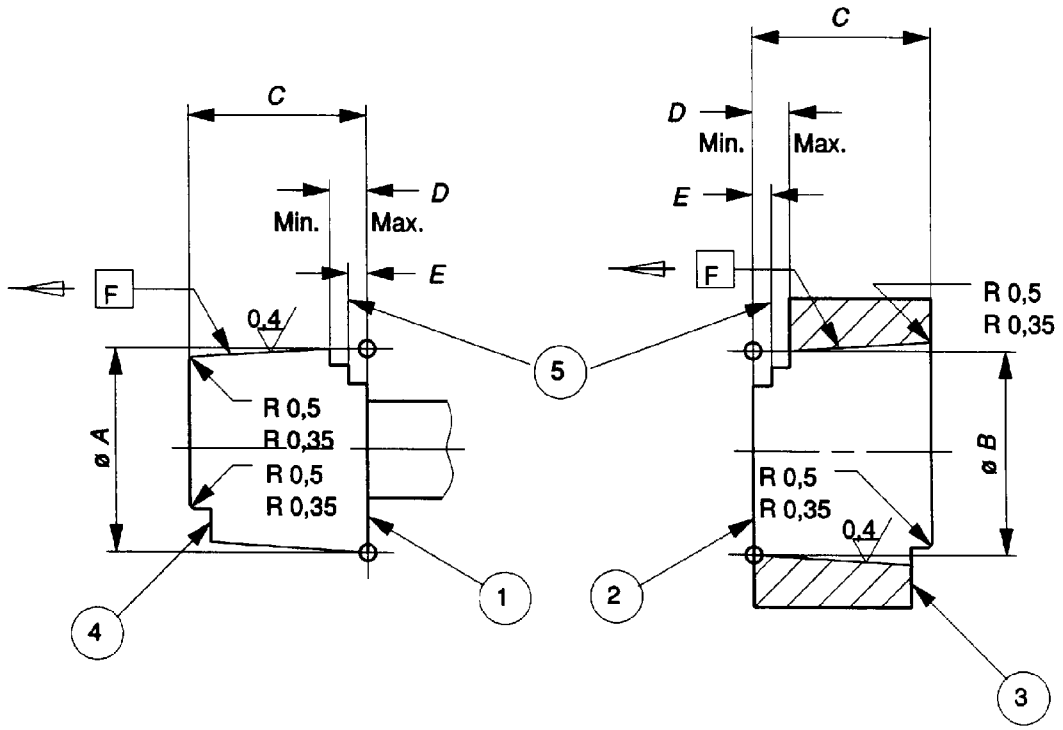

2. Circumferential grooves may be incorporated on the surface of the male cone, if required (see **6.3.2**)

Figure 2b). Connector intended for face mask (with shoulder)

**Figure 2. Conical connector of 22 mm size made of metal — supplementary dimensions**

## Annex A (informative)
## Plug and ring test gauges for conical connectors made of metal

Dimensions in millimetres: surface roughness values in micrometres




1. Face A
2. Face B
3. Step to check mating gauges ground flush to face A
4. Step to check mating gauges ground flush to face B
5. Basic steps

NOTE. Basic and mating gauge steps are optional.

**Figure A.1 Plug and ring test gauges for conical connectors made of metal**

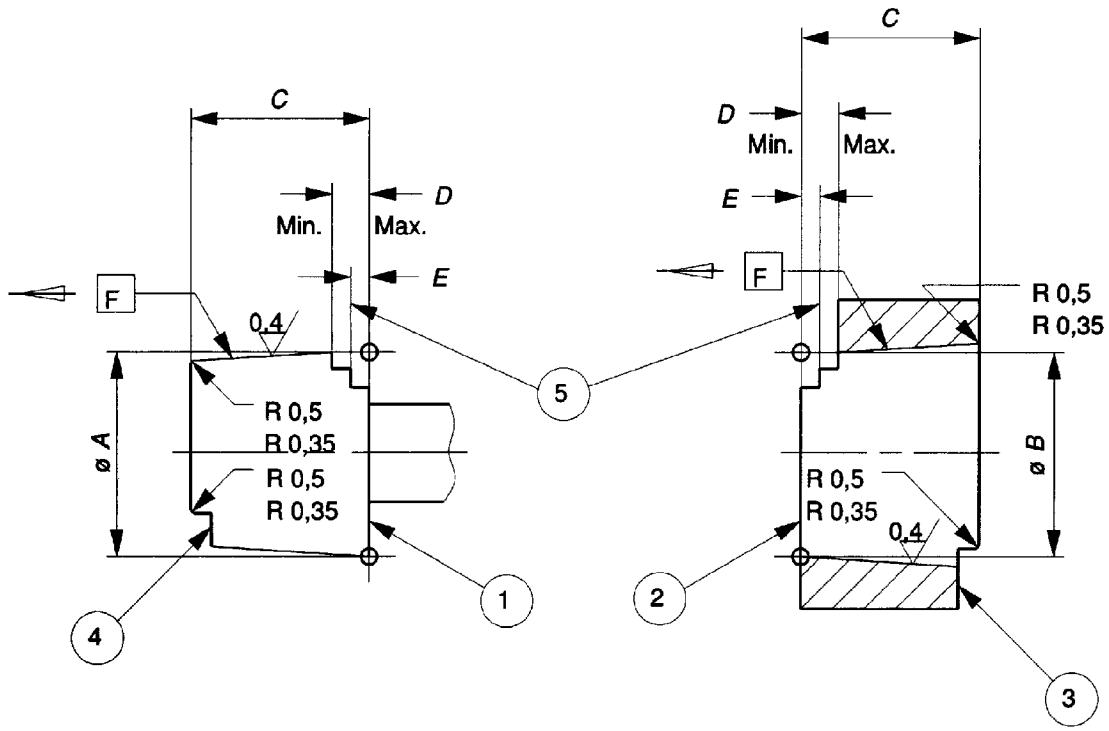
**Table A.1 Plug and ring test gauges for conical connectors made of metal — Dimensions**

| Connector | A (mm) | B (mm) | C (mm) | D (mm) | E (mm) | F | Tolerance on taper per unit of length on diameter |
|---|---|---|---|---|---|---|---|
| 8,5 mm | 8,49 ± 0,005 | 8,094 ± 0,05 | 8,4 ± 0,005 | 1,52 ± 0,005 | See note | 1:19 | ± 0,0002 |
| 15 mm | 15,51 ± 0,005 | 15,18 ± 0,005 | 14,5 ± 0,05 | 3 ± 0,005 | 1,6 ± 0,005 | 1:40 | ± 0,0002 |
| 22 mm | 22,41 ± 0,005 | 21,955 ± 0,005 | 19,5 ± 0,005 | 3 ± 0,005 | 1,6 ± 0,005 | 1:40 | ± 0,0002 |
| 23 mm | 23,195 ± 0,003 | 22,794 ± 0,003 | 16 ± 0,005 | 1,33 ± 0,005 | 0,72 ± 0,005 | 1:36 | ± 0,0002 |
| 30 mm | 30,95 ± 0,005 | 30,15 ± 0,005 | 17 ± 0,005 | 1,9 ± 0,005 | 1 ± 0,005 | 1:20 | ± 0,0002 |

NOTE. Gauge for 8,5 mm connector has only one mating step

## Annex B (normative)
## Plug and ring test gauges for conical connectors made of material other than metal

Dimensions in millimetres: surface roughness values in micrometres




1. Face A
2. Face B
3. Step to check mating gauges ground flush to face A
4. Step to check mating gauges ground flush to face B
5. Basic steps

NOTE. Basic and mating gauge steps are optional.

**Figure B.1 Plug and ring test gauges for conical connectors made of materials other than metal**

**Table B.1 Plug and ring test gauges for conical connectors made of materials other than metal — Dimensions**

| Connector | A (mm) | B (mm) | C (mm) | D (mm) | E (mm) | F | Tolerance on taper per unit of length on diameter |
|---|---|---|---|---|---|---|---|
| 8,5 mm | 8,50 ± 0,005 | 8,09 ± 0,005 | 8,4 ± 0,005 | 1,31 ± 0,005 | See note | 1:19 | ± 0,0002 |
| 15 mm | 15,525 ± 0,005 | 15,165 ± 0,005 | 14,5 ± 0,005 | 4,3 ± 0,005 | 2,2 ± 0,005 | 1:40 | ± 0,0002 |
| 22 mm | 22,425 ± 0,005 | 21,94 ± 0,005 | 19,5 ± 0,005 | 5,2 ± 0,005 | 2,2 ± 0,005 | 1:40 | ± 0,0002 |
| 30 mm | 30,98 ± 0,005 | 30,12 ± 0,005 | 15 ± 0,005 | 3,1 ± 0,005 | 1,6 ± 0,005 | 1:20 | ± 0,0002 |

NOTE. Gauge for 8,5 mm connector has only one mating step.

## Annex C (normative)

## Method of test for security of engagement of latching connector of 22 mm size to male conical connector

**C.1** Condition a male 22 mm conical connector complying with figure 2a) and the latching connector for 1 h at a temperature of (35 ± 3) °C and relative humidity of at least 80 % RH and carry out the test under the same conditions.

**C.2** Engage the latching connector with the male connector in accordance with the manufacturer's instructions.

**C.3** After 1 min of engagement without activation of any disengagement mechanism, apply an axial separation force at a rate not exceeding 20 $N \cdot s^{-1}$ until a force of (50 ± 5) N is being applied and maintain that force for 10 s and, unless the latching connector permits free radial rotation, apply also a torque of (25 ± 5) N·cm.

**C.4** Observe whether the assembled connectors become disconnected.

NOTE. Examples of suitable apparatus that can be used, together with a more detailed test procedure, are given for information in annex F.

## Annex D (normative)

## Method of test for leakage from latching connectors

**D.1** Take the engaged male conical connector and latching connector that have been tested as described in annex C and maintain them at (35 ± 3) °C.

**D.2** Using air, apply an internal static air pressure of (8 ± 0,5) kPa above ambient to the assembly and determine the leakage rate from the assembly, e.g. by pressure drop or volumetric methods.

## Annex E (normative)

## Drop procedure for latching connectors

**E.1** Pre-condition a male conical connector complying with figure 2a) and the latching connector for 1 h at a temperature of (20 ± 3) °C and relative humidity of at least 80 % RH and carry out the test under the same conditions.

**E.2** Engage the latching connector with the male conical connector in accordance with the manufacturer's instructions. Attach the male conical connector to a breathing tube complying with prEN 12342 and having a length of 2 m.

**E.3** Attach the opposite end of the breathing tube to a point 1 m above a 50 mm thick hardwood board (e.g. hardwood having a density greater than 700 $kg/m^3$) standing on a rigid base (e.g. a concrete block).

**E.4** Raise the latched male and female connectors to a height of 1 m and release them so that they fall onto the hardwood board. Repeat this five times.

## Annex F (informative)

## Suggested apparatus and methods for testing for security of engagement of latching connectors

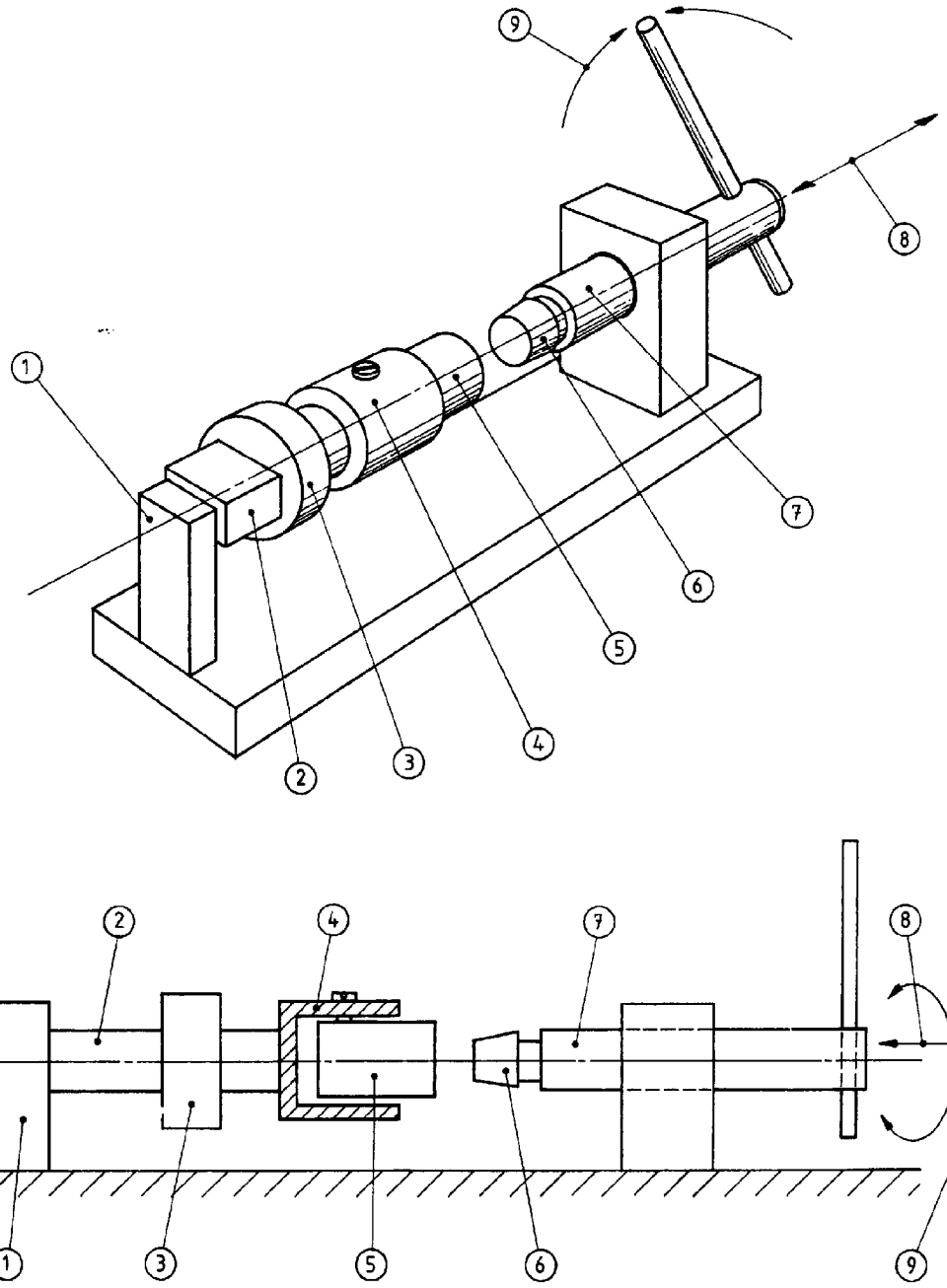
### F.1 Method 1 — Bench-mounted test equipment

#### F.1.1 *Apparatus*

An example of an apparatus is shown in figure F.1. The male test piece should be a 22 mm male conical connector dimensioned as shown in figure 2a) but with all the tolerances reduced to ± 0,005 mm and a surface finish of 0,4 µm.

NOTE. There are a number of methods of applying the test forces and figure F.1 is illustrative of only one approach. Other methods include the use of gravity loading by weights or liquid containers.

The essential features are to ensure that the tensile force can be applied in a truly axial direction and that torque can be applied without changing the tensile force. To minimize the effects of the friction of the apparatus, the tensile force should be measured directly between the two halves of the joint under test.




1. Rigid support
2. Axial load meter
3. Torque meter
4. Holder
5. Connector under test
6. 22 mm male test piece
7. Free to slide and rotate
8. Apply adjustable axial force
9. Apply adjustable torque

**Figure F.1 Apparatus for testing for security of engagement of latching connectors (method 1 — bench-mounted)**

**F.1.2 *Procedure***

**F.1.2.1** Secure the latching connector to be tested in the self-centring holder of the apparatus (**F.1.1**), ensuring that the method of securing the latching connector does not deform the section(s) that are intended to engage with the male test piece.

**F.1.2.2** Condition the latching connector and the apparatus at a temperature of (35 ± 3) °C and a relative humidity of at least 80 % RH for 1 h.

NOTE. If a number of latching connectors are to be tested, some may be conditioned at the required temperature and relative humidity without being secured to the apparatus provided that they are conditioned for at least 5 min after being secured to the apparatus.

**F.1.2.3** Engage the latching connector with the male test piece in accordance with the manufacturer's instructions.

**F.1.2.4** After 1 min, attach the force measuring device and apply an axial separation force at a rate not exceeding 20 $N \cdot s^{-1}$ until a force of (50 ± 5) N is being applied. Maintain this force for 10 s without activating any disengagement mechanism and observe whether the engaged latching connector and male test pieces become disconnected.

**F.1.2.5** Without reducing the tensile load and without activation of any disengagement mechanism, apply a torque of (25 ± 5) N·cm or rotate the male test piece through an angle of 20°, whichever occurs first. Maintain this torque or position for 10 s and observe whether the engaged latching connector and male test piece become disconnected.

**F.2 Method 2 — Hand-held test equipment**

**F.2.1 *Apparatus***

An example of an apparatus is shown in figure F.2.

**F.2.2 *Procedure***

**F.2.2.1** Condition the latching connector and the apparatus (**F.2.1**) at a temperature of (35 ± 3) °C and a relative humidity of at least 80 % RH for 1 h.

**F.2.2.2** Engage the latching connector with the male test piece on the apparatus in accordance with the manufacturer's instructions.

**F.2.2.3** After 1 min, manually apply an axial separation force at a rate not exceeding 20 $N \cdot s^{-1}$ until a force of (50 ± 5) N is being applied. Maintain this force for 10 s without activation of any disengagement mechanism and observe whether the engaged latching connector and male test piece become disconnected.

**F.2.2.4** Without reducing the tensile load, and without activation of any disengagement mechanism, apply a torque of (25 ± 5) N·cm or rotate the male test piece through an angle of 20°, whichever occurs first. Maintain this torque or position for 10 s and observe whether the engaged latching connector and male test piece become disconnected.

**F.2.2.5** Repeat the procedure described in clause **F.2.2.4** with the torque applied in the opposite direction.

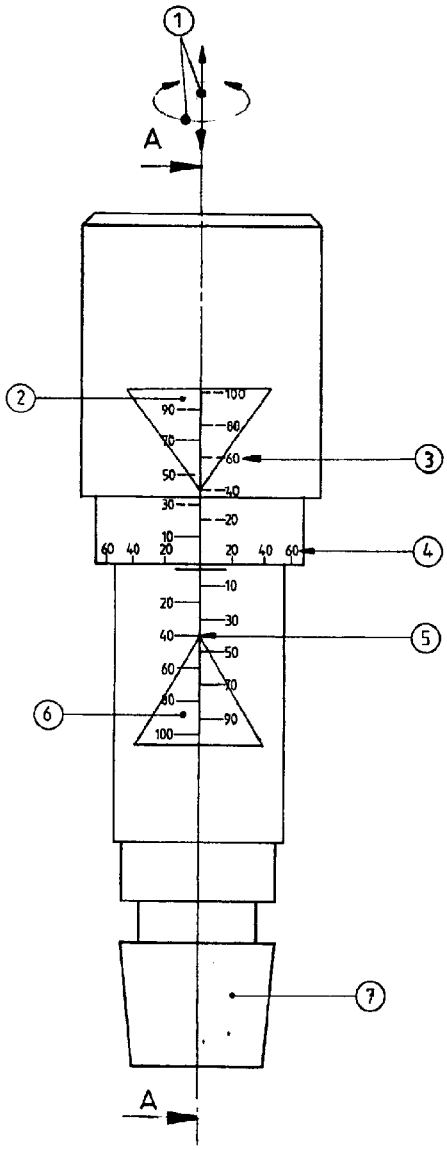



Figure F.2a). External view

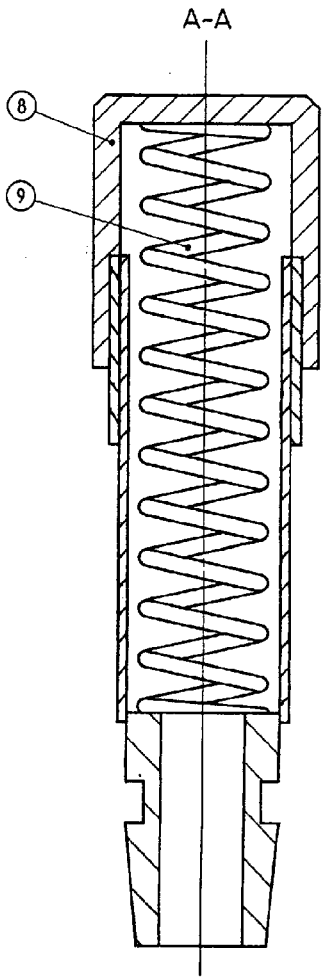



Figure F.2b). Sectional view

1. Hold knob in hand; apply torque or push or pull by hand
2. Area indicating acceptable pull and twist
3. Pull force scale
4. Torque scale
5. Push force scale
6. Area indicating acceptable push and twist
7. 22 mm male test piece
8. Knob
9. Coil spring fixed at both ends

NOTE. Torque and force scales pre-calibrated using apparatus in figure F.1.

**Figure F.2 Apparatus for testing for security of engagement of latching connectors (method 2 — hand-held)**

## Annex G (informative)
## Bibliography


| | |
|---|---|
| prEN 740 : 1992 | *Medical electrical equipment — Anaesthetic workstations and their modules — Particular requirements* |
| prEN 794-1 | *Medical electrical equipment — Lung ventilators — Particular requirements — Part 1 : Lung ventilators for medical use* |
| ISO 1302 : 1992 | *Technical drawings — Method of indicating surface texture on drawings* |
| ISO 3040 | *Technical drawings — Dimensioning and tolerancing — Cones* |
| ISO 5366-1 | *Tracheostomy tubes — Part 1 : Connectors for tubes for adults* |
| ISO 7228 | *Tracheal tube connectors* |
| ISO 8185 | *Humidifiers for medical use — Safety requirements* |


## Annex ZA (informative)
## Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

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**Table ZA.1 Correspondence between this European Standard and EU Directives**

| Clause/subclause of this European Standard | Corresponding Essential Requirement of Directive 93/42/EEC | Comments |
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| 4 | | Refers reader to device standards |
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| 9 | | Refers reader to device standards regarding marking |
| 10 | 13.1, 13.3a), b), c), d), e), f), j), k), l), m), 13.4, 13.6a), c), d) | |
| 10a | 13.6k) | |
| 10b | 8.7, 13.3m), 13.6h) | |
| 10c | 5, 7.2, 8.3, 8.6, 13.3i), 13.6i) | |
| 10d | 7.2, 8.3, 13.6g) | |
| 10e | 13.6n) | |

N/A = not applicable

## Annex G (informative)
## Bibliography


| | |
|---|---|
| prEN 740 : 1992 | *Medical electrical equipment — Anaesthetic workstations and their modules — Particular requirements* |
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**BS EN 1281-1 : 1997**

Issue 2, December 1998

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**Amendment No. 1**
**published and effective from 15 December 1998**
**to BS EN 1281-1 : 1997**

# Anaesthetic and respiratory equipment — Conical connectors

## Part 1. Cones and sockets

## Instructions for replacement of pages

The following pages contain new or revised text. Please remove any superseded pages and insert the new or revised pages in the position given in the summary of pages (see page a). Where only one of the two pages on each sheet has been updated, the other page has been reprinted.

Front cover and inside front cover

a

ii

EN title page and page 2

3

5

Inside back cover and back cover

You may wish to retain the superseded pages, e.g. for reference purposes. If so please mark them "Superseded by issue X", where "X" is the appropriate issue number. If you do not wish to retain the superseded pages, please destroy them.

BRITISH STANDARD

**BS EN 1281-1 : 1997**

*Incorporating Amendment No. 1*

# Anaesthetic and respiratory equipment — Conical connectors

## Part 1. Cones and sockets

The European Standard EN 1281-1 : 1997, with the incorporation of its amendment A1 : 1998, has the status of a British Standard

ICS 11.040.10

# Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/44, Anaesthetic machines, breathing attachments, medical gas pipeline systems and hose assemblies, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
Association of British Health-care Industries
British Anaesthetic and Respiratory Equipment Manufacturers' Association
Department of Health

The following body was also represented in the drafting of the standard, through a subcommittee/panel:

Guild of Hospital Pharmacists

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 May 1997



**Amendments issued since publication**

| Amd. No. | Date | Text affected |
|---|---|---|
| 10094 | December 1998 | Indicated by a sideline |
| | | |
| | | |
| | | |

The following BSI references relate to the work on this standard:
Committee reference CH/44
Draft for comment 93/509495 DC

**ISBN 0 580 27386 5**

## Summary of pages

The following table identifies the current issue of each page. Issue 1 indicates that a page has been introduced for the first time by amendment. Subsequent issue numbers indicate an updated page. Vertical sidelining on replacement pages indicates the most recent changes (amendment, addition, deletion).

| Page | Issue | Page | Issue |
|---|---|---|---|
| Front cover | 2 | 2 | 2 |
| Inside front cover | 2 | 3 | 2 |
| a | 1 | 4 | original |
| b | blank | 5 | 2 |
| i | original | 6 to 12 | original |
| ii | 2 | Inside back cover | 2 |
| EN title page | 2 | Back cover | 2 |

# Contents

# National foreword

This British Standard has been prepared by Technical Committee CH/44 and is the English language version of EN 1281 *Anaesthetic and respiratory equipment — Conical connectors* — Part 1 : 1997 *Cones and sockets*, including Amendment A1 : 1998, published by the European Committee for Standardization (CEN).

This standard supersedes BS 3849 : Part 1 : 1988 which is withdrawn. Together with BS EN 1281-2 : 1996, this standard supersedes BS 3849 : Part 2 : 1988 which is withdrawn.

## Cross-references

| International Standard | Corresponding British Standard |
|---|---|
| EN ISO 4135 : 1996 | BS EN ISO 4135 : 1996 *Glossary of terms used in anaesthesiology* (Identical) |
| EN 60601-1 : 1990 | BS 5724 *Medical electrical equipment* Part 1 : 1989 *General requirements for safety* (Identical) |

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1281-1

January 1997

+ A1

May 1998

ICS 11.040.10

Descriptors: Medical equipment, anaesthetic equipment, artificial breathing apparatus, fittings, conical clamping connections, specifications, dimensions, dimensional measurements, standard gauges, junctions, tests, marking

English version

# Anaesthetic and respiratory equipment — Conical connectors — Part 1 : Cones and sockets

(includes amendment A1 : 1998)

Matériel respiratoire et d'anesthésie — Raccords coniques — Partie 1 : Raccords mâles et femelles (inclut l'amendement A1 : 1998)

Anästhesie- und Beatmungsgeräte — Konische Konnektoren — Teil 1 : Männliche und weibliche Konen (enthält Änderung A1 : 1998)

This European Standard was approved by CEN on 1996-12-15; amendment A1 was approved by CEN on 1998-05-03. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Comité Européen de Normalisation
Europäisches Komitee für Normung

**Central Secretariat: rue de Stassart 36, B-1050 Brussels**



Ref. No. EN 1281-1 : 1997 + A1 : 1998 E

## Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This European Standard is based on ISO 5356-1 : 1993, prepared by Technical Committee ISO/TC 121 of the International Organization for Standardization (ISO).

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EU directives, see informative annex ZA, which is an integral part of this standard.

This European Standard applies to conical connectors for anaesthetic and respiratory equipment and has been prepared in two Parts. This Part addresses cones and sockets; Part 2 addresses screw-threaded weight-bearing connectors.

Annexes B, C, D and E are normative and form part of this European Standard. Annexes A, F, G and ZA are for information only.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

## Foreword to amendment A1

This Amendment EN 1281-1 : 1997/A1 : 1998 to EN 1281-1 : 1997 has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This Amendment to the European Standard EN 1281-1 : 1997 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

This Amendment to the European Standard EN 1281-1 : 1997 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 1998, and conflicting national standards shall be withdrawn at the latest by November 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

## Contents

## Introduction

This European Standard specifies dimensional requirements for conical connectors used in anaesthetic and respiratory equipment.

The standard comprises two Parts:

Part 1 : Cones and sockets

Part 2 : Screw-threaded weight-bearing connectors.

In clinical practice several breathing attachments may have to be joined together to provide a suitable breathing system. Items of medical equipment, such as a humidifier or a spirometer, are often incorporated into the breathing system which may also be connected to an anaesthetic gas scavenging system. Connections for these purposes are usually, though not invariably, cone and socket joints and a lack of standardization of these connections has given rise to problems of interchangeability when connecting equipment made by different manufacturers.

This Part of the standard gives the requirements for the following conical connectors:

- 8,5 mm sizes intended for use in paediatric breathing systems;[1)]
- 15 mm and 22 mm sizes intended for general use in breathing systems;[2)]
- 23 mm size intended for use with vaporizers[3)], which are unsuitable for use in breathing systems;
- 30 mm size intended for the connection of a breathing system to an anaesthetic gas scavenging system.[4)]

An important consideration is that conical connections should be secure but nevertheless disconnectable by the operator. The use of connectors meeting the requirements of this Part of the standard will not necessarily prevent them being disconnected accidentally.

This Part of this European Standard specifies the performance of latching connectors of 22 mm size.

Annex A (informative) includes a figure and a table detailing plug and ring test gauges that may be used to check the sizes of metal conical connectors. It is provided for information only and is not a normative part of the standard.

Annex B (normative) includes a figure and a table detailing plug and ring test gauges that are used to check the sizes of conical connectors made of materials other than metal.

Figure 1 detailing the dimensions and tolerances of metal conical connectors has been prepared in accordance with the principles given in ISO 3040.

Requirements and application of conical connectors are not included in this Part of this European Standard but are given in particular European Standards for specific medical devices and accessories (see notes and annex G (informative)).

## 1 Scope

This Part of this European Standard specifies dimensional and gauging requirements for cones and sockets and performance requirements for latching connectors intended for use in medical devices, e.g. in breathing systems, anaesthetic gas scavenging systems and vaporizers.

This European Standard does not specify the medical devices and accessories on which these connectors are to be provided.

NOTE 1. It is expected that requirements on the use of suitable materials and for the application of this standard will be included in particular standards for specific medical devices and accessories.

NOTE 2. Requirements for screw-threaded weight-bearing conical connectors are specified in Part 2 of this standard.

## 2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

| | |
|---|---|
| EN ISO 4135<br>(ISO 4135 : 1995) | *Anaesthesiology vocabulary* |
| prEN 12342 | *Breathing tubes intended for use with anaesthetic apparatus and ventilators* |
| EN 60601-1 : 1990<br>(IEC 601-1 : 1988) | *Medical electrical equipment Part 1: General requirements for safety* |

[1)] See e.g. EN 1780 and bibliography.

[2)] See e.g. clause **63.1.7.1** and **66** of prEN 740 : 1992 and bibliography.

[3)] See e.g. clause **64.1.1** of prEN 740 : 1992 and bibliography.

[4)] See e.g. clause **70.5** of prEN 740 : 1992 and bibliography.

## 3 Definitions

For the purposes of this European Standard, the following definition applies, in addition to those given in EN ISO 4135.

### 3.1 latching connector

Female connector for engagement with a male conical connector complying to this standard, which has a feature to reduce the possibility of accidental disconnection.

## 4 Antistatic and electrically conductive connectors

See appropriate device standards for specific requirements.

## 5 Materials

See appropriate device standards for specific requirements.

## 6 Conical connectors made of metal

### 6.1 General requirements

The dimensions of conical connectors made of metal shall be as shown in figure 1, figure 2 and table 1.

NOTE 1. See annex A for dimensions of plug and ring gauges.

NOTE 2. Metal connectors include those made of composite materials in which the mating surfaces are metal.

NOTE 3. Conical connectors of 30 mm size are intended for use for the connection of a breathing system to a anaesthetic gas scavenging system.

### 6.2 Additional requirements for conical connectors of 8,5 mm size

The male conical connector shall have a minimum inside diameter of 6 mm extending inward for at least 6 mm from the end of the connector.

### 6.3 Additional requirements for conical connectors of 22 mm size

**6.3.1** Male conical connectors of 22 mm size, with the exception of those intended for connection to a face mask, shall incorporate the recess as shown in figure 2a).

NOTE. The recess shown in figure 2a) is to accommodate the end of a female connector made of elastomeric material[5] or to permit the fitting of other devices to improve the attachment of the socket to the male conical connector e.g. a latching connector (see clause 8).

**6.3.2** All male connectors to which it is intended to attach a face mask shall incorporate a shoulder or equivalent construction as in figure 2b).

**6.3.3** If a circumferential groove or grooves are incorporated in the surface of such a male conical connector, the total width of the groove or grooves at the surface shall not exceed 8 mm.

## 7 Conical connectors made of materials other than metal

### 7.1 General requirements

Conical connectors, made of materials other than metal shall meet the following requirements when they are type tested with gauges having dimensions as shown in figure B.1 and table B.1.

a) Conical connectors made of materials other than metal shall meet the dimensional requirements in figure 1 and table 1 with the exception that dimensions A, B and F may be varied from those shown.

b) When the connector is engaged in the appropriate plug or ring test gauge shown in figure B.1 and table B.1, by applying an axial force of $(35 \pm 3{,}5)$ N for 8,5 mm and 15 mm connectors and $(50 \pm 5)$ N for 22 mm and 30 mm connectors and, while maintaining the same force, rotating the connector up to 20°, its leading edge shall lie between the minimum and maximum diameter steps of the gauge. The connectors and gauges shall be maintained at a temperature of $(20 \pm 3)$ °C during the test.

NOTE. Because connectors made from plastics materials, for example from polyamide, polyacetal, polycarbonate, polysulfone, etc., may vary greatly in their physical characteristics, it is not considered practicable to specify their dimensions; for this reason, gauging requirements have been included. It is also considered impracticable to generalize on matters such as cold flow and thermal instability as well as possible changes in physical characteristics, contact with solvents, etc. It is, therefore, the responsibility of the manufacturer to ensure that adequate tests have been carried out to prove as far as possible that the particular materials are suitable. See also the note to clause 5.

### 7.2 Additional requirements for conical connectors of 8,5 mm size

The requirements of clause 6.2 apply.

### 7.3 Additional requirements for conical connectors of 22 mm size

The requirements of clause 6.3 apply.

## 8 Latching connectors of 22 mm size

**8.1** The latching connector of 22 mm size shall engage with the 22 mm male connector with a recess as specified in figure 2a).

---

[5] The term 'elastomeric material' includes soft rubber (natural or synthetic) and some soft plastic materials, for example polyvinyl chloride, low-density polyethylene and silicone rubber.

**8.2** When tested as described in annex C the engaged connection shall not become disconnected.

**8.3** When tested as described in annex D the leakage from the engaged connectors shall not exceed 5 ml/min (corrected to 20 °C and 101,3 kPa).

**8.4** After being subjected to the procedure described in annex E the latching connector shall still meet the requirements specified in clauses **8.1, 8.2 and 8.3.**

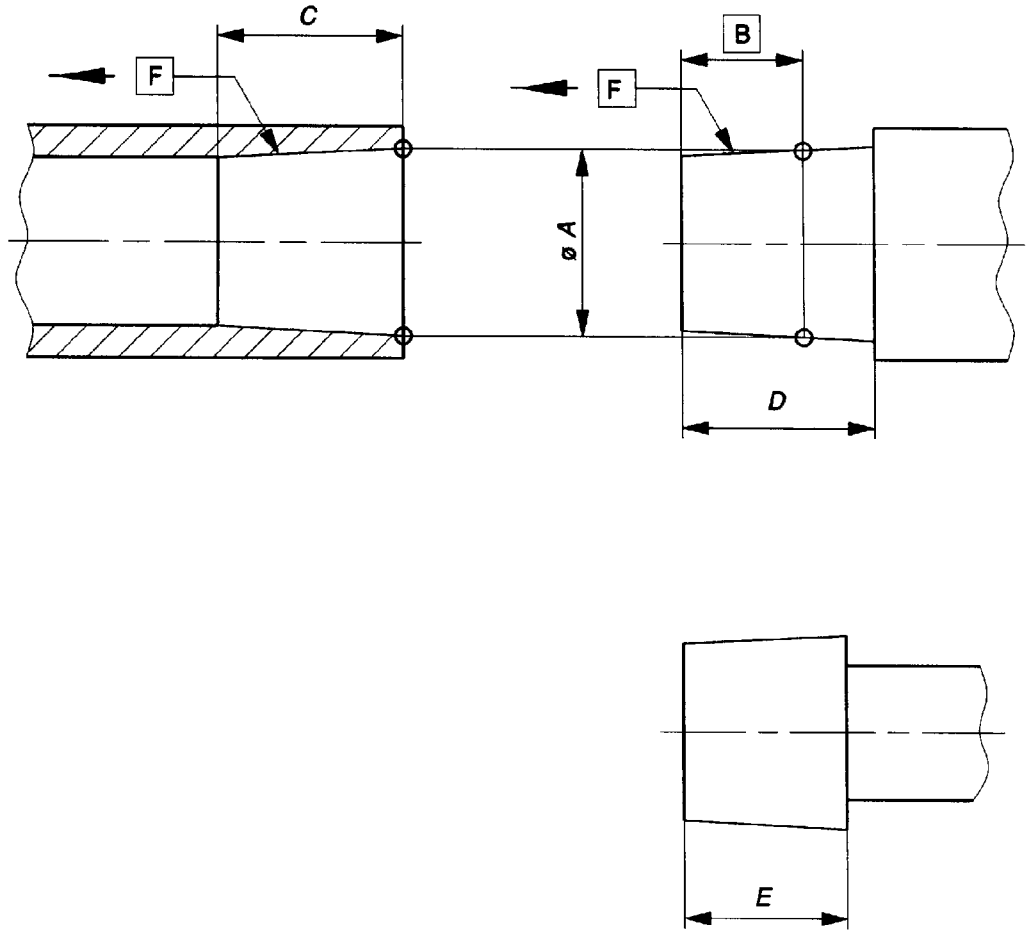
**8.5** Latching connectors intended for re-use shall meet the requirements specified in clauses **8.1, 8.2, 8.3** and **8.4** after being subjected to the cleaning, disinfection or sterilization procedures specified in clause **44.7** of EN 60601-1.

## 9 Marking

See appropriate device standards for specific requirements.

## 10 Information to be supplied by the manufacturer

See appropriate device standards for specific requirements.



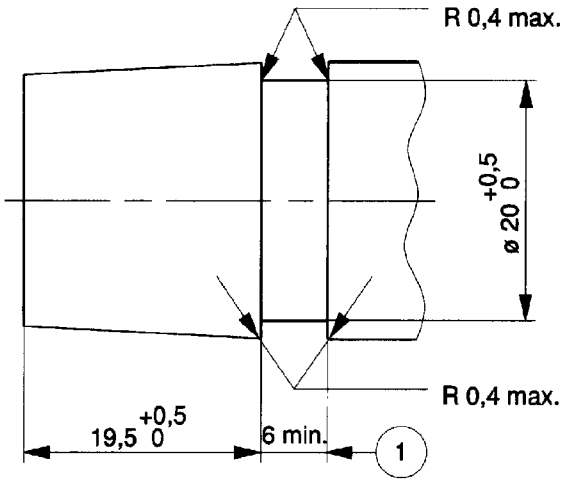

Dimensions in millimetres

NOTE. Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0,8 mm and not be less than 0,5 mm for 22 mm cones and sockets. For all other cones and sockets it should not exceed 0,5 mm and not be less than 0,2 mm.

**Figure 1. Conical connectors made of metal — Dimensions**

**Table 1. Conical connectors made of metal — Dimensions**

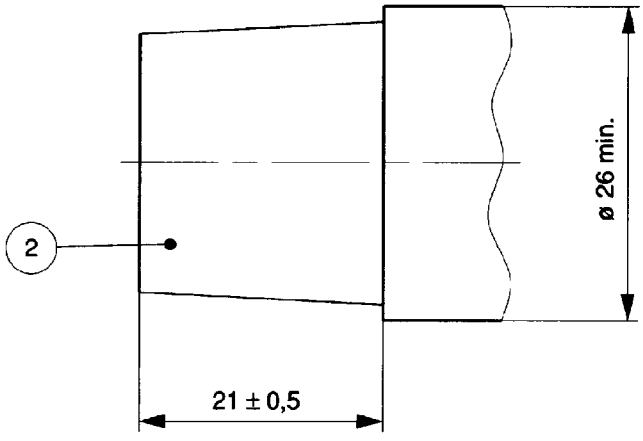
| Connector | A (mm) | B (mm) | C Min. length of taper (mm) | D Clearance to shoulder (if present) (mm) | E Min. length of taper (mm) | F |
|---|---|---|---|---|---|---|
| 8,5 mm | 8,45 ± 0,04 | 6 | 6,4 | 8,9 min. | 8 | 1:19 |
| 15 mm | 15,47 ± 0,04 | 10 | 16 | 16 min. | 14,5 | 1:40 |
| 22 mm | 22,37 ± 0,04 | 15 | 21 | See figure 2 | See figure 2 | 1:40 |
| 23 mm | 23,175 ± 0,02 | 13 | 18 | 18 min. | 15 | 1:36 |
| 30 mm | 30,9 ± 0,05 | 14 | 18 | 18 min. | 14 | 1:20 |




Dimensions in millimetres

1. To shoulder (if present)

Figure 2a). Connector intended for breathing attachment (with recess)




2. Circumferential grooves may be incorporated on the surface of the male cone, if required (see **6.3.2**)

Figure 2b). Connector intended for face mask (with shoulder)

**Figure 2. Conical connector of 22 mm size made of metal — supplementary dimensions**

## Annex G (informative)
## Bibliography


| | |
|---|---|
| prEN 740 : 1992 | *Medical electrical equipment — Anaesthetic workstations and their modules — Particular requirements* |
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**BS EN 1281-1 : 1997**

Issue 2, December 1998

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